

EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
Media and Reagent Preparation: Assigning Prep and Sterilization Run Numbers

SOP Number: QC-15-03

Date Revised: 10-31-05

Initiated By: _____ Date: ____/____/____

Print Name: _____

Technical Review: _____ Date: ____/____/____

Print Name: _____

Technical Staff

QA Review: _____ Date: ____/____/____

Print Name: _____

QA Officer

Approved By: _____ Date: ____/____/____

Print Name: _____

Branch Chief

Effective Date: ____/____/____

Controlled Copy No.: _____

Withdrawn By: _____ Date: ____/____/____

TABLE OF CONTENTS

<u>Contents</u>	<u>Page Number</u>
1.0 SCOPE AND APPLICATION.....	2
2.0 DEFINITIONS.....	2
3.0 HEALTH AND SAFETY.....	2
4.0 CAUTIONS.....	2
5.0 INTERFERENCES.....	2
6.0 PERSONNEL QUALIFICATIONS.....	2
7.0 SPECIAL APPARATUS AND MATERIALS.....	2
8.0 INSTRUMENT OR METHOD CALIBRATION.....	2
9.0 SAMPLE HANDLING AND STORAGE.....	2
10.0 PROCEDURE AND ANALYSIS.....	2
11.0 DATA ANALYSIS/CALCULATIONS.....	3
12.0 DATA MANAGEMENT/RECORDS MANAGEMENT.....	3
13.0 QUALITY CONTROL.....	4
14.0 NONCONFORMANCE AND CORRECTIVE ACTION.....	4
15.0 REFERENCES.....	4
16.0 FORMS AND DATA SHEETS.....	4

1.0 SCOPE AND APPLICATION:

- 1.1 This protocol describes the procedures used to assign media/reagent preparation and sterilization batch control numbers. Tracking media and reagents from preparation to use must be thoroughly documented.

2.0 DEFINITIONS: None

3.0 HEALTH AND SAFETY: Not applicable

4.0 CAUTIONS: None

5.0 INTERFERENCES:

- 5.1 The suffix on all preparations is critical for the tracking of all preparations and its assignment must be made by following the SOP explicitly.

6.0 PERSONNEL QUALIFICATIONS:

- 6.1 Personnel must be knowledgeable of the procedures for assigning preparation and sterilization batch control numbers. Documentation of training and familiarization with this SOP can be found in the training file for each employee.

7.0 SPECIAL APPARATUS AND MATERIALS: None

8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable

9.0 SAMPLE HANDLING AND STORAGE:

- 9.1 Media and reagents are subject to proper storage as specified by the manufacturer.

10.0 PROCEDURE AND ANALYSIS:

- 10.1 When preparing media and reagents, completion of the Media/Reagent Preparation Sheet and Media/Reagent Preparation Log Form is required (see 16.0).
- 10.2 All media and reagents will be assigned a preparation control number. The preparation control number consists of two parts: 1) the first seven digits represent the date the media or reagent was prepared: PMMDDYY where P=Prepared, MM=month, DD=day, and YY=the last two digits of the calendar

year; and 2) the suffix, where the digits after the dash act as a counter for the number of preparations made on the same date. For example, the first preparation made on April 29, 2005 would have the control number P042905-01. The next item prepared on that same day would have a suffix of -02; the third preparation made on that same day would have a suffix of -03, etc.

- 10.3 For all media and reagents that are sterilized by autoclaving, a sterilization batch number is assigned. The procedure for assigning the sterilization batch number follows similar notation for assigning preparation control numbers. The sterilization batch number consists of two parts: 1) the first seven digits represent the date the batch was sterilized: SMMDDYY where S=Sterilization, MM=month, DD=day, and YY=the last two digits of the calendar year; and 2) the suffix where the first digit after the dash indicates the autoclave used and the next two digits act as a counter for the number of preparations made on the same date. For example, the first batch sterilized on April 29, 2005 in autoclave 1 (rm B206) would have the control number S042905-101. The next batch sterilized on that same day and same autoclave would have a suffix of -102; the third batch sterilized would have a suffix of -103; etc. (autoclave 1=B206, autoclave 2=B204, autoclave 3=B207, autoclave 4=B202, autoclave 5=D122).
- 10.4 The Media/Reagent Preparation sheet identifies information relevant to the preparation of the media or reagent. The preparation sheet may also be used for non-media items that require a preparation number such as glass slide carriers, porcelain carriers, and steel carriers.
- 10.5 All boxes on the Media/Reagent Preparation sheet must be filled out with the appropriate information for that section. If a section is not applicable to the item being prepared, place N/A (Not Applicable) in that section.
- 10.6 Record the storage requirement for the media at the bottom of the page. If the material is to be used immediately and requires no storage, then place N/A in that section.
- 11.0 DATA ANALYSIS/CALCULATIONS: None
- 12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:
 - 12.1 Data will be recorded promptly, legibly, and in indelible ink on the appropriate forms. Completed forms are archived in notebooks kept in secured file cabinets in the file room D217. Only authorized personnel have access to the secured files. Archived data is subject to OPP's official retention schedule contained in

SOP ADM-03, Records and Archives.

13.0 QUALITY CONTROL:

13.1 For quality control purposes, the required information is documented on the appropriate form(s) (see 16.0).

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 If a preparation control number or sterilization batch number is missing and cannot be determined from the Media/Reagent Preparation Sheet (see 16.1), or the Daily Sterilization Record Information Log Form (see 16.2), the media or reagent will not be used in any testing procedure and will be discarded.

15.0 REFERENCES: None

16.0 FORMS AND DATA SHEETS:

16.1 Media/Reagent Preparation Sheet

16.2 Media/Reagent Preparation Log Form

16.3 Daily Sterilization Record Information Log Form

MEDIA/REAGENT PREPARATION SHEET OPP MICROBIOLOGY LABORATORY

Media/Reagent Name: Prep #:

Amount Prepared: Preparation Date/Initials:

pH Meter #:	Dispenser: (circle one)	Water Bath #(s):	BSC #(s):	Sterilization #:
	Hamilton Oxford Hand NA			

Media/Chemical Ingredients:	Control No:	Amount Required:	Amount Weighed:

Preparation/Modifications/Notes:

Required pH:	Original pH:	Final pH:	Temperature:
Volume of Acid/Base added to obtain final pH:			

Sterility/Viability Test Results	Sterility	Viability
	Pass Fail	Pass Fail

Storage of Reagent/Media:

Media Requested by: _____

Media Prepared for: ATP R&D PIP

Media/Reagent Preparation Log Form

OPP Microbiology Laboratory

[illegible]

Daily Sterilization Record Information Log Form

OPP Microbiology Laboratory

[illegible]

- 1 Record the cycle as "G" = gravity, "L" = liquid under Type and the duration of the cycle in minutes under Time.
- 2 Record the maximum and minimum temperature achieved during the sterilize phase of the cycle as indicated by the autoclave printout (Unit).
- 3 Record the corrected value for the maximum registering thermometer (Max.) and the serial number of the thermometer.
- 4 Record the results of the chemical indicator strips as "P" for pass or "F" for fail.
- 5 The Sterilization No. indicates the date as well as the unit location and the run number.